BACKGROUND: Chronic kidney disease (CKD) is highly prevalent in type 2 diabetes mellitus (T2DM) population. However, information regarding recent temporal trends and prevalence within key demographic subgroups are lacking. **OBJECTIVES:** To estimate the prevalence of CKD stages in T2DM over time and within demographic subgroups. **METHODS:** Individuals ≥18 years old with T2DM were identified from the US National Health and Nutrition Examination Survey (NHANES) 2007-2012 via either self-reported diabetes or antidiabetic medication use. Individuals with type 1 diabetes, pregnancy, and with missing serum creatinine lab value, age, gender, or race were excluded. CKD was staged based on KDIGO 2012 guidelines as: 1=estimated glomerular filtration rate (eGFR in ml/min/1.73m2 via CKD-Epi equation) ≥90 with albuminuria; 2=60-89 with albuminuria; 3a=45-59; G3b=30-44; 4=15-29; 5=<15. Projected national estimates are reported using appropriate NHANES weights to account for non-response bias and oversampling. **RESULTS:** Of the 2,006 T2DM individuals, the overall age-adjusted CKD prevalence from 2007-2012 was 38.3%: 40.2% in 2007-2008, 36.9% in 2009-2010, and 37.6% in 2011-2012. Most CKD patients were at early stages (77.5% for Stages 1 to 3a), with only 22.5% with moderate to severe CKD (Stages 3b to 5). Over the 3 survey cycles, the prevalence of Stage 3a increased while Stage 1 and 2 decreased. The prevalence of CKD in patients with T2DM was 25.7% in <65 years old, 58.7% in ≥65 years old, 40.0% in males, 38.7% in females, 43.5% in both Blacks and Mexican Americans, and 38.7% in Whites. **CONCLUSIONS:** Our findings, in this nationally representative population, highlight that CKD, primarily early stages, is prevalent among a large group of T2DM patients, particularly Blacks and Mexican-Americans, for whom interventions may be targeted in order to slow and/or prevent the progression of kidney function decline. Patients not aggressively targeted for CKD screening, such as younger patients, also warrant attention.

PDB31

COMPARISON OF REAL-WORLD HYPOGLYCEMIA RATES AMONG PATIENTS INITIATING TREATMENT WITH SAXAGLIPTIN OR GLIPIZIDE

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OBJECTIVES: This study compared hypoglycemia rates in patients with type 2 diabetes on metformin who augmented treatment with saxagliptin or glipizide 5-20 mg/day. **METHODS:** This retrospective analysis utilized US healthcare claims data from the Truven Health MarketScan Research Databases. Data were from adults on metformin monotherapy who added saxagliptin or glipizide 5-20 mg/day between 1 August 2009 and 31 December 2010. Hypoglycemia event rates were compared during the 4 months after initiation of saxagliptin or glipizide. A hypoglycemia event was defined as a diagnosis of hypoglycemia on an outpatient or emergency room claim, a principal diagnosis on a hospital claim, or a glucagon injection in an outpatient setting. Analyses were adjusted for patient demographics and clinical characteristics using inverse propensity score weights and rate ratios were computed using bivariate Poisson regression. To achieve maximal covariate balance in adjusted analyses, only patients with a propensity score ≥0.02 were retained for analysis. **RESULTS:** A total of 9,246 patients (1,567 taking saxagliptin; 7,679 taking glipizide) qualified. During 120 days of follow-up, there were 205 hypoglycemia events. Most of the hypoglycemia events (93.2%) occurred in the outpatient setting. There were no inpatient or emergency room hypoglycemia events in the saxagliptin cohort. The overall unadjusted rate of hypoglycemia was significantly lower in the saxagliptin cohort than in the glipizide cohort (1.74 vs. 7.73 per 100 person-years; p<0.001; rate ratio=0.23 [95% confidence interval=0.10-0.44]). After applying inverse propensity score weights (N=8,241), the adjusted rate of hypoglycemia also was significantly lower in the saxagliptin cohort versus the glipizide cohort (1.74 vs. 4.18 per 100 person-years; p=0.002; rate ratio=0.42 [95% confidence interval=0.24-0.71]). **CONCLUSIONS:** Treatment with saxagliptin was associated with a lower risk of hypoglycemia compared with glipizide 5-20 mg/day in a real-world database. These results add confidence to similar findings from clinical trials.

PDB32

ASSOCIATION BETWEEN BONE MINERAL DENSITY AND TYPE 1 DIABETES MELLITUS: A META-ANALYSIS OF OBSERVATIONAL STUDIES

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OBJECTIVES: Diabetes influences bone metabolism, but the relation of type 1 diabetes mellitus (T1DM) with bone mineral density (BMD) remains inconsistent across studies. The objective of this study was to perform a meta-analysis to estimate the difference in BMD between T1DM and non-diabetic populations. **METHODS:** Studies were selected by doing comprehensive literature search in PubMed and EMBASE up to January 2014. Additional searches were also conducted to include research abstracts, cross references and bibliography of individual articles. All studies, including cross-sectional, cohort or case–control design, showing association between T1DM and BMD measured by dual energy X-ray absorptiometry (DEXA) were considered eligible for the review. A random effects meta-analysis was performed. Heterogeneity and publication bias were checked. Results are expressed as Pearson correlations. **RESULTS:** The analysis was done on 48 observational studies reporting 2,885 cases and 4,814 controls. Meta-analysis showed that BMD in T1DM patients was significantly lower, with pooled mean differences of -0.43 (95% CI: -0.69, -0.17) in women and -0.25 (95% CI: -0.50, -0.005) in men at the hip region. It was also found significantly lower at the spine region [-0.30 (95% CI: -0.47, -0.13)] in men and forearm region [-0.21 (95% CI: -0.43, 0.00)] in women. No siginificant difference was found in BMD (in both men and women) between in case of femoral neck region. Sensitivity analysis confirmed the stability of our results. **CONCLUSIONS:** Our analysis confirmed that both men and women with T1DM have preponderence to have lower BMD levels. Multiple factors (age/gender/menopausal status/bone type) can influence BMD in individuals with T1DM. Large prospective epidemiological studies are required to confirm our findings.

PDB33

WITHDRAWN

PDB34

CHANGES IN THE SAFETY PROFILE OF ORAL DIABETES MEDICATIONS APPROVED BY THE FDA

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OBJECTIVES: The increase in the prevalence of type-2 diabetes has resulted in a substantial increase in the utilization of oral diabetes drugs in the US. This study assessed changes in the safety profile of the oral diabetes medications approved by the US Food and Drug Administration (FDA) as of December 31, 2014. **METHODS:** Regulatory information for oral diabetes medications as of December 31 was derived from the FDA webpage. Label information was extracted from the FDA webpage and paper copies of the PDR Book. Drugs were classified according to the WHO anatomical therapeutic chemical classification. Descriptive statistics and chi-square tests were used for the analysis. **RESULTS:** The FDA listed a total of 44 oral diabetes medications as of December 31, 2014, including 30 single active ingredients and 14 fixed-dose combinations. Three of the single active ingredients and 1 of the combinations were discontinued from the market as of December 31, 2014. In total, 15.9% of the drugs were approved before 1990, 22.7% in the 1990s, 36.4% in the 2000s, and 25.0% in 2010-2014. The main changes in safety profile of the drugs included in the study occurred in contraindications (changes in 50.0% of the drugs), limitations (38.6%), warning and precautions (36.4%), and black box warnings (20.5%). Additionally, changes also occurred in the indications approved by the FDA for 31.8% of the drugs. Changes in safety profile did not significantly varied according to the year of approval of a drug; however, drugs approved in the period 2010-2014 had a lower number of safety changes due to the limited time these drugs have been in the market. **CONCLUSIONS:** This study found substantial changes over time in the safety profile of oral diabetes drugs. Future research should evaluate the effect of changes in the safety profile of oral diabetes medication on patient outcomes.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB35

MODELING THE LONG TERM ECONOMIC BENEFITS OF A PATIENT-ADJUSTED MEALTIME INSULIN TITRATION ALGORITHM AMONG PATIENTS WITH TYPE 2 DIABETES IN THE UNITED STATES

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OBJECTIVES: Despite being the most efficacious blood glucose lowering therapy, the majority of patients on basal insulin do not achieve adequate glycemic control (HbA1c<7.0%), increasing the risk of complications. A patient-adjusted mealtime insulin-dosing algorithm was recently validated in a randomized clinical trial (AUTONOMY) and demonstrated statistically significant and clinically meaningful reductions in HbA1c (-1.0%). The goal of our study was to estimate the longer term economic outcomes of this clinical trial treatment effect in a representative sample of US patients with Type 2 diabetes. **METHODS:** We utilized a validated Monte Carlo microsimulation model to compare patients initiating the AUTONOMY daily (Q1D) titration algorithm upon HbA1c drift to those delaying initiation. Outcomes modeled included mean HbA1c, diabetes-related complications, mortality, and associated costs over 10 years. Treatment effects were modeled from AUTONOMY clinical trial results. The setting for the economic analysis was representative of the care delivered within the general population of patients utilizing insulin within the US (NHANES). Sensitivity analyses included factors such as time horizon, discount rate, and baseline HbA1c. **RESULTS:** Patients initiating self-adjusted bolus titration upon HbA1c drift had better outcomes over the 10 years: decreases of -1.3% in severe hypoglycemic events, -2.8% in myocardial infarction or cardiac events, -1.8% in stroke, -6.9% in blindness, -12.4% in lower extremity amputations, and -1.7% in mortality. These patients were estimated to have a small increase in pharmacy

costs ($347) due to longer lifetimes, and had a direct medical cost reduction (-$1,716) due to improved glycemic control. **CONCLUSIONS:** The AUTONOMY Q1D titration algorithm offers a simple and effective approach to assist patients requiring basal-bolus therapy in adjusting their meal-time insulin dose. Results from our study indicate that compared to published delays in treatment modification or escalation, an adaptive daily titration algorithm can lead to better outcomes at lower costs.

PDB36

COST-EFFECTIVENESS ANALYSIS AND BUDGET IMPACT OF AN EXTENDED VERSUS IMMEDIATE RELEASE FORMULATION OF METFORMIN IN TYPE-2 DIABETES MELLITUS TREATMENT, FROM THE PERSPECTIVE OF THE BRAZILIAN PUBLIC HEALTH SYSTEM

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OBJECTIVES: The IDF global guideline for type-2 DM considers metformin as first-line therapy, without contraindications, but gastrointestinal intolerance occurs in 20-30% of patients receiving an immediate release of metformin, being a possible barrier to treatment adherence. Glucophage® XR is an extended-release formulation of metformin IR, with the same antidiabetic efficacy, a flexible dosing range to assist in treatment titration with superior gastrointestinal tolerability, contributing to greater compliance. The aim of this study is to evaluate the cost-effectiveness (CE) and budget impact (BI) of metformin XR compared to metformin IR, in adults with type-2 DM, from the perspective of the public health system in Brazil. **METHODS:** The outcomes of interest were days on treatment; number of events (stroke, myocardial infarction, heart failure, peripheral mononeuropathy, retinopathy, blindness, diabetic foot, amputation, diabetic nephropathy and renal disease); number of full-lifetime-patients without treatment (non-compliance); number of full-lifetime-patients with controlled diabetes; and life years. Efficacy data were obtained from literature review and unit costs were obtained from official price lists. The time horizon of the CE and BI model was 30 and 10 years respectively. A 5% annual discount rate was applied to costs and benefits in the CE model. **RESULTS:** Glucophage® XR increased overall survival in 0.75 day and assured more 1,631 days on treatment, per patient, during lifetime period. Also, reduced 6,249 events and allowed more 143 full-lifetime-patients with controlled type-2 DM, per 1,000 patients. Glucophage® XR was dominant vs. Metformin IR, resulting in saving approximately 5.5% (BRL 10,961,011 per patient). Additionally, the use of Glucophage® XR in patients with type-2 DM resulted in saving of approximately BRL 3,787,758,740.88 in the period from 2014 to 2025. **CONCLUSIONS:** Glucophage® XR showed dominance versus metformin IR due to a safer profile leading to better tolerance, compliance and better health outcomes.

PDB37

DIRECT MEDICAL COSTS ASSOCIATED WITH DIABETIC COMPLICATIONS IN PATIENTS WITH TYPE 2 DIABETES IN THE US VERSUS SOUTH KOREA

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OBJECTIVES: To estimate and compare annual direct medical costs associated with diabetic complications in patient with type 2 diabetes in the USA and South Korea. **METHODS:** Data were obtained from the 2010-2011 Medical Expenditure Panel Survey (MEPS), which is a nationally representative sample of ambulatory population in the US, and the 2010-2011 Korea Health Panel (KHP) which contains health service use and expenditures for a representative sample of Korea. Using ICD-9 CM codes, patients were classified as patients with microvascular complications only (nephropahty, neuropathy, retinopahty, or peripheral vascular disease), macrovascular complications only (cardiovascular disease and cerebrovascular disease), both complications, and without complications. Direct medical costs included costs associated with hospitalization, outpatient visits, emergency room visits, and drugs. To compare costs of diabetic patients with and without complications, direct medical costs were estimated using the generalized linear model (GLM) with log link function and gamma distribution after adjusting for patient characteristics. **RESULTS:** Among 3,864 and 2,060 patients with diabetes in the US and Korea, respectively, 87.0% and 61.9% patients had no complications; 4.5% and 17.7% patients had microvascular complications only; 8.3% and 13.6% had macrovascular complications only; and 0.2% and 6.8% had both complications. The average annual direct medical costs per patient were $8,191 in the US and $1,590(US$1=KRW1,000) in Korea. After adjusting for patients' characteristics, annual direct medical costs associated with microvascular complications were 2.36(US) and 2.05(Korea) times greater; macrovascular complications were 2.70(US) and 1.76 times(Korea) greater, while both complications were 5.66(US) vs. 3.08(Korea) times greater than those without complications, respectively. **CONCLUSIONS:** Direct medical treatment costs in patients with diabetic microvascular or macrovascular complications were significantly higher than those without diabetes complications, and the magnitudes of additional costs are different between US and Korea. Providing proper treatment of diabetes to prevent or delay diabetic complications is important to minimize treatment costs of diabetes.

PDB39

ECONOMIC IMPACT OF DAPAGLIFLOZIN VS. OTHER ANTIDIABETIC DRUGS FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The objective of this study was to evaluate the short-term economic impact of treatment of type 2 diabetes (T2DM) patients with dapagliflozin (dapa) vs. other antidiabetic drugs, including daily dosage glucagon-like peptide-1 (GLP-1) agonists, dipeptidyl peptidase-4 (DPP-4) inhibitors, thiazolidinediones (TZDs), and sulfonylureas (SUs). **METHODS:** An economic model (1-year time horizon) was developed to evaluate differences in annual medical costs and costs per quality-adjusted life-year (QALY) gain among T2DM patients treated with dapa vs. other antidiabetic drugs. Changes in clinical endpoints, including HbA1c, weight, systolic blood pressure (SBP), and hypoglycemia risk, associated with 52-week treatment with the different antidiabetic drugs were obtained from a network meta-analysis. Annual medical costs and QALYs for changes in clinical endpoints were obtained from published literature. **RESULTS:** For one year of treatment of a T2DM patient, medical costs associated with changes in HbA1c, weight, SBP, and hypoglycemia risk for dapa were -$173 (Confidence interval: -$1,125, $747) vs. GLP-1 agonists, -$1,061 (-$1,859, -$362) vs. DPP-4 inhibitors, -$1,524 (-$2,552, -$649) vs. TZDs, and -$2,300 (-$3,131, -$1,574) vs. SUs. Results from univariate and multivariable sensitivity analyses showed that the estimates of the medical cost differences were most affected by variations in weight and SBP changes, but were generally robust when model parameters were varied. Treatment with dapa was cost saving vs. other antidiabetic drugs when only medical costs were considered. When drug costs were included, treatment with dapa remained either cost saving (vs. GLP-1 agonists and DPP-4 inhibitors) or cost-effective vs. TZDs ($10,007 per QALY), vs. SUs ($9,650 per QALY). **CONCLUSIONS:** Treatment of T2DM patients with dapa was associated with reduced medical costs vs. daily dosage GLP-1 agonists, DPP-4 inhibitors, TZDs, and SUs. When drug costs were included, treatment with dapa was cost saving vs. daily dosage GLP-1 agonists and DPP-4 inhibitors and cost-effective vs. TZDs and SUs.

PDB40

EVALUATION OF THE ANNUAL COST OF MEDICINES USED IN TREATMENT OF TYPE 2 DIABETES MELLITUS IN INDIA

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OBJECTIVES: To compute the cost of medicines used in the treatment of T2DM and study the variation in the costs. **METHODS:** Indian Council of Medical Research (ICMR) and International Diabetes Federation (IDF) guidelines were used to understand the treatment of T2DM. Current Index of Medical Specialities (CIMS) Apr-July2014 issue and Indian Drug Review (IDR) issue 2, Feb2014 were used to capture the prices of medicines available in the Indian market. The annual cost of treatment and variation in the annual cost of drugs was studied. **RESULTS:** IDF recommends first line treatment with metformin 500mg twice a day. The annual cost of treatment with metformin was found to be Rs.467-2336. A variation of 400% is noted in the least-highest cost of metformin. Glimepiride 2mg OD is used as a second line treatment and its annual cost ranges between Rs.458-4851. It shows maximum variation of 960% in the least-highest cost. Likewise, third line treatment can be started either with α-Glucosidase inhibitor or DPP4 inhibitor or Thiazolidine group of drugs. Annual cost of treatment with Pioglitazone 15mg was found to be Rs.365-2555. Among the third line category of drugs, Pioglitazone 15mg shows maximum variation of 600% in the least-highest cost. Used as a fixed dose combination (FDC), Glimepiride+Metformin (1+500 mg) showed maximum price variation of 529%. **CONCLUSIONS:** It was concluded that a maximum of 11 fold variation was observed in the least-highest costs of treatment with Glimepiride 2mg in the year 2014. Wide variation exists in the percentage price variation of same drug manufactured across the different brands.

PDB41

ECONOMIC BURDEN AND POOR QUALITY OF LIFE ASSOCIATED WITH ACROMEGALY IN THE UNITED STATES

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OBJECTIVES: To assess economic burden and quality of life (QoL) associated with acromegaly in the United States. **METHODS:** A web-based cross-sectional survey was conducted from August –October, 2014. Patient-reported information on acromegaly-related economic burden was collected. The direct and indirect costs per patient over the past 3 months included out-of-pocket cost, sick leave, leave of absence, direct loss of job due to acromegaly, unemployment, assistance to perform household chores, and family member loss of income. The QoL was assessed by Acromegaly Quality of Life (AcroQoL) and EQ-5D questionnaires. Descriptive analysis was used. **RESULTS:** A total of 106 patients completed the survey (mean age: 46 years, female: 76%). The annualized office visits per person to physicians, nurses and other health professionals was 11.8, 3.4 and 6.6 visits, respectively. The acromegaly patients had 0.7 emergency room visits, 0.3 hospital admissions and length of hospital stay of 1.8 days. Annualized healthcare out-of pocket cost was $1,790/person. The average number of days unable to work was 34 days with estimated income loss $6,702 /person-year. The average annual loss of income due to direct loss of job, unemployment disability, household chores, and income loss of family members was $6,106, $10,653, $1,685, and $472/person, respectively. As compared with low-symptom group, symptom 0-3 (n=41), the high-symptom group with 4+ symptoms (n=65) had significantly higher costs by category (loss of job: $8,876 vs. $1,717, p=0.017; unemployment disability: $17,102 vs. $429, p=0.003; household chores: $540 vs. $233, p=0.0003; family members' loss: $128 vs. $23, p=0.028). The average EQ-5D index score and global score of AcroQoL were 0.62±0.23 and 38.61±22.39, respectively. Patients reporting 4 + symptoms had lower QoL scores as compared with those with fewer symptoms (EQ-5D: 0.53 vs. 0.75, p<0.0001; AcroQoL: 27.38 vs. 56.43, p<0.0001). **CONCLUSIONS:** Patients with acromegaly experienced high economic burden and poor quality of life.

PDB42

ESTIMATING CLINICAL AND ECONOMIC OUTCOMES FOLLOWING A DIABETES-RELATED VASCULAR COMPLICATION

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OBJECTIVES: Type 2 diabetes mellitus (T2DM) is a prevalent disease affecting over 25 million people in the United States. Diabetes inflicts a heavy economic burden